Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 31. Illegal Payments; Required Disclosures of Financial Interests

Subchapter A. General Information

§3101. Scope and Purpose of Chapter

- A. Scope of Chapter. The rules of this chapter interpret, implement, and provide for the enforcement of R.S. 37:1744 and R.S. 37:1745, or their successors, requiring disclosure of a pharmacist's financial interest in another health care provider to whom or to which the pharmacist refers a patient and prohibiting certain payments in return for referring or soliciting patients.
- B. Declaration of Purpose; Interpretation and Application. Pharmacists owe a fiduciary duty to patients to exercise their professional judgment in the best interests of their patients in providing, furnishing, recommending, or referring patients for health care items or services. The purpose of these rules and the laws they implement is to prevent payments by or to a pharmacist as a financial incentive for the referral of patients to a pharmacist or other health care provider for healthcare services or items. These rules shall be interpreted, construed, and applied so as to give effect to such purposes and intent.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2112 (October 2003), effective January 1, 2004, repromulgated LR 34:2158 (October 2008).

§3103. Definitions

A. As used in this Chapter, the following terms have the meaning ascribed to them by this section: *Board* – the Louisiana Board of Pharmacy.

Financial Interest – a significant ownership or investment interest established through debt, equity, or other means and held, directly or indirectly, by a pharmacist or a member of a pharmacist's immediate family, or any form of direct or indirect remuneration for referral. Group Practice – a group of two or more pharmacists and/or other health care providers legally organized as a general partnership, registered limited liability partnership, professional medical corporation, limited liability company, foundation, nonprofit corporation, faculty practice plan, or similar organization or association:

- a. in which each pharmacist who is a member of the group provides substantially the full range of services which the pharmacist routinely provides;
- b. for which substantially all of the services of the pharmacists who are members of the group are provided through the group and are billed under a billing number assigned to the group and amounts so received are treated as receipts of the group;
- c. in which no pharmacist who is a member of the group directly or indirectly receives compensation based on the volume or value of referrals by the pharmacist, except payment of a share of the overall profits of the group, which may include a productivity bonus based on services personally performed or services incident to such personally performed services, so long as the share of profits or bonus is not determined in any manner which is directly related to the volume or value of referrals by such pharmacist; and
- d. in the case of a faculty practice plan associated with a hospital, institution of higher education, or pharmacy school with an approved training program in which pharmacist members may provide a variety of different specialty services and provide professional services both within and outside the group, as well as perform other tasks such as research, solely with respect to services provided within such faculty practice plan.

Health Care Item – any substance, product, device, equipment, supplies, or other tangible good or article which is or may be used or useful in the provision of health care.

Health Care Provider – any person, partnership, corporation, or association licensed by a department, board, commission, or other agency of the state of Louisiana to provide, or which does in fact provide preventive, diagnostic, or therapeutic health care services or items.

Immediate Family – as respects a pharmacist, the pharmacist's spouse, children, parents, siblings, stepchildren, stepparents, in-laws, grandchildren, and grandparents.

Investment Interest – a security issued by an entity, including, without limitation, shares in a corporation, interests in or units of a partnership or limited liability company, bonds, debentures, notes, or other debt instruments.

Payment – transfer or provision of money, goods, services, or anything of economic value. *Person* – as defined in R.S. 37:1164(33). or its successor.

Pharmacist – any individual currently licensed by the board to engage in the practice of pharmacy in the state of Louisiana.

Pharmacy – any place where drugs are dispensed and pharmacy primary care is provided. Referral – any direction, recommendation, or suggestion given by a health care provider to a patient, directly or indirectly, which is likely to determine, control, or influence the patient's choice of another health care provider for the provision of health care services or items. Remuneration for Referral – any arrangement or scheme, involving any remuneration, directly or indirectly, in cash or in kind, between a pharmacist, or an immediate family member of such pharmacist, and another health care provider that is intended to induce referrals by the pharmacist to the health care provider or by the health care provider to the pharmacist, other than any amount paid by an employer to an employee who has a bona fide employment relationship with the employer, for employment in the furnishing of any health care item or service. Significant Financial Interest – an ownership or investment interest shall be considered "significant", within the meaning of §3113, if such interest satisfies any of the following tests:

- a. Such interest, in dollar amount or value, represents five percent or more of the ownership or investment interests of the health care provider in which such interest is held; or
- b. Such interest represents five percent or more of the voting securities of the health care provider in which such interest is held.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2112 (October 2003), effective January 1, 2004, repromulgated LR 34:2158 (October 2008).

Subchapter B. Illegal Payments

§3105. Prohibition of Payments for Referrals

- A. A pharmacist or pharmacy shall not knowingly and willfully make, or offer to make, any payment, directly or indirectly, overtly or covertly, in cash or in kind, to induce another person to refer an individual to the pharmacist for the furnishing, or arranging for the furnishing, of any health care item or service.
- B. A pharmacist or pharmacy shall not knowingly and willfully solicit, receive, or accept any payment, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient to a health care provider for the furnishing, or arranging for the furnishing, of any health care item or service.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2113 (October 2003), effective January 1, 2004, repromulgated LR 34:2159 (October 2008).

§3107. Prohibited Arrangements

A. Any arrangement or scheme, including cross-referral arrangements, which a pharmacist or pharmacy knows or should know has a principal purpose of ensuring or inducing referrals by the pharmacist to another health care provider, which, if made directly by the pharmacist or pharmacy would be a violation of §3113, shall constitute a violation of §3113.

AUTHORITY NOTE: Promulgated in accordance with R.S. 38:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2113 (October 2003), effective January 1, 2004, repromulgated LR 34:2159 (October 2008).

§3109. Exceptions

- A. Proportionate Return on Investment. Payments or distributions by an entity representing a direct return on investment based upon a percentage of ownership, shall not be deemed a payment prohibited by R.S. 37:1745(B), or its successor, or §3105 of these regulations.
- B. General Exceptions. Any payment, remuneration, practice, or arrangement which is not prohibited by or unlawful under §1128(b) of the Federal Social Security Act (Act), 42 U.S.C. §1320a-7b(b), or its successor, with respect to health care items or services for which payment may be made under Title XVIII or Title XIX of the Act, including those payments and practices sanctioned by the secretary of the United States Department of Health and Human Services, through the Office of the Inspector General, pursuant to §1128B(b)(3)(E) of the Act, through regulations promulgated at 42 CFR §1001.952, or its successor, shall not be deemed a payment prohibited by R.S. 37:1745(B), or its successor, or by §3105 of these rules with respect to health care items or services for which payment may be made by any patient or private or governmental payor.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2113 (October 2003), effective January 1, 2004, repromulgated 34:2159 (October 2008).

§3111. Effect of Violation

A. Any violation of, or failure of compliance with, the prohibitions and provision of §3105 of this chapter shall be deemed a violation of the Pharmacy Practice Act, R.S. 37:1161 et seq, providing cause for the board to sanction a person culpable of such violation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2113 (October 2003), effective January 1, 2004, repromulgated LR 34:2160 (October 2008).

Subchapter C. Disclosure of Financial Interests in Third-Party Health Care Providers

§3113. Required Disclosure of Financial Interest

A. Mandatory Disclosure. A pharmacist or pharmacy shall not make any referral of a patient outside the pharmacist's or pharmacy's group practice for the provision of health care items or services by another health care provider in which the referring pharmacist has a financial interest, unless, in advance of any such referral, the referring pharmacist or pharmacy discloses to the patient, in accordance with §3113 of this chapter, the existence and nature of such financial interest.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 17:780 (August 1991), amended LR 29:2113 (October 2003), effective January 1, 2004, repromulgated LR 34:2160 (October 2008).

§3115. Form of Disclosure

- A. Required Contents. The disclosure required by §3113 of this chapter shall be made in writing, shall be furnished to the patient, or the patient's authorized representative, prior to or at the time of making the referral, and shall include:
 - 1. the pharmacist's or pharmacy's name, address, and telephone number;
 - 2. the name and address of the health care provider to whom the patient is being referred by the pharmacist or pharmacy;

- 3. the nature of the items or services which the patient is to receive from the health care provider to which the patient is being referred; and
- 4. the existence and nature of the pharmacist's or pharmacy's financial interest in the health care provider to which the patient is being referred.
- B. Permissible Contents. The form of disclosure required by §3113 of this chapter may include a signed acknowledgment by the patient or the patient's authorized representative that the required disclosure has been given.
- C. Approved Form. Notice to a patient given substantially in the form of Disclosure of Financial Interest prescribed in the Appendix to this rule shall be presumptively deemed to satisfy the disclosure requirements of this subchapter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2113 (October 2003), effective January 1, 2004, repromulgated LR 34:2160 (October 2008).

§3117. Effect of Violation; Sanctions

- A. Effect of Violation. Any violation of, or failure of compliance with, the prohibitions and provision of \$3113 of this chapter shall be deemed a violation of the Pharmacy Practice Act, R.S. 37:1161 et seq., providing cause for the board to sanction a pharmacist or pharmacy culpable of such violation.
- B. Administrative Sanctions. In addition to the sanctions provided for by R.S. 37:1241, upon proof of violation of §3113 by a pharmacist or pharmacy, the board may order that all or any portion of any amounts paid by a patient, and/or by any third-party payor on behalf of a patient, for health care items or services furnished upon a referral by the pharmacist or pharmacy in violation of §3113, be refunded by the pharmacist or pharmacy to such patient and/or third-party payor, together with legal interest on such payments at the rate prescribed by law calculated from the date on which any such payment was made by the patient and/or third-party payors.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2114 (October 2003), effective January 1, 2004, repromulgated 34:2160 (October 2008).

§3119. Disclosure of Financial Interest

[Name of Pharmacist/Group] [Address] [Telephone Number]

DISCLOSURE OF FINANCIAL INTEREST As Required by R.S. 37:1744 and LAC 46:LIII.3113-3115

TO:	DATE:
(Name of Patient to Be Referred)	
(Patient Address)	
they refer a patient to another health care provide	ealth care providers to make certain disclosures to a patient when ider or facility in which the pharmacist has a significant financial d patient for whom you are legal representative, to:
(Name and Address of Provider to Whom	n Patient is Referred)
to obtain the following health care services, produ	ucts, or items:
(Purpose of the Referral)	
[I/we] have a financial interest in the health care which are as follows:	e provider to whom we are referring you, the nature and extent of
PATIENT A	ACKNOWLEDGEMENT
I, the above-named patient, or legal representative and prior to the described referral, of a copy of the	re of such patient, hereby acknowledge receipt, on the date indicated the foregoing Disclosure of Financial Interest.
Signature of Patient or Patient's Represen	ntative)
AUTHORITY NOTE: Promulgated in accordance HISTORICAL NOTE: Promulgated by the Depa	ce with R.S. 37:1182. artment of Health and Hospitals, Board of Pharmacy, LR 29:2114

(October 2003), effective January 1, 2004, repromulgated 34:2160 (October 2008).

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